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In re the Application of: **Garvey et al**

Application No: **09/478,222**

Group Art Unit: **1627**

Filed: **January 5, 2000**

Examiner: **B. Celsa**

For: **Nitrosated and Nitrosylated Alpha-Adrenergic Receptor Antagonists, Compositions and Methods of Use**

#5  
AKO  
4-17-01

Attorney Docket No: **102258.346**

Assistant Commissioner of Patents  
Washington, DC 20231

**Provisional Response to Restriction Requirement and  
Request for Reconsideration of Restriction Requirement Under 37 C.F.R. §1.143**

This response is submitted in reply to the Restriction Requirement dated March 22, 2001, for which a response is due on or before April 22, 2001. No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees to Deposit Account No. 08-0219 to maintain the pendency of the present application.

**I. Request for Reconsideration of Restriction Requirement**

Under 37 C. F. R. 1.143, Applicants respectfully request reconsideration of the restriction requirement dated March 22, 2001.

The examiner restricted the invention seven-ways to claims 35-69 as follows:

Group I	Claims 35-42	Compositions comprising NO containing compounds (nucleotides, proteins) for the treatment of impotence
Group II	Claims 43-47	Compositions comprising compounds that induce endogenous NO production for the treatment of impotence
Group III	Claims 48-52	Compositions comprising 2-hydroxy-2-nitrosohydrazine for the treatment of impotence

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Group IV	Claims 53-56	Compositions comprising (E)-alkyl-2-((E)-hydroximino)-5-nitro-3-hexene amine/amide for the treatment of impotence
Group V	Claims 57-60	Compositions comprising sydnonimine compounds for the treatment of impotence
Group VI	Claims 61-65	Compositions comprising S-nitrosothiol compounds for the treatment of impotence
Group VII	Claims 66-69	Compositions comprising NONOate compounds for the treatment of impotence

The claims in the grandparent application, U. S. Serial No. 08/714,313, issued as U. S. Patent 5,994,294, has claims directed to:

1. Compounds and compositions comprising a nitrosated/nitrosylated compound of Formula II.
2. Compositions comprising (i) a nitrosated/nitrosylated compound of Formula II and (ii) a NO generating compound.
3. Methods for the treatment of male impotence by administration of a composition comprising a nitrosated/nitrosylated compound of Formula II.
4. Methods for the treatment of male impotence by administration of a composition comprising (i) a nitrosated/nitrosylated compound of Formula II and (ii) a NO generating compound.

In the grandparent application, U. S. Patent 5,994,294, Examiner Celsa allowed claims that included the nitrosated/nitrosylated compound of Formula II in combination with all nitric oxide donors (i.e., a compound donates, transfers or releases nitrogen monoxide, induces the production of endogenous endothelium-derived relaxing factor, stimulates endogenous synthesis of nitrogen monoxide or is a substrate for nitric oxide synthase). In the present application, the claims are directed to the nitric oxide donor compounds alone (i.e. without the nitrosated/nitrosylated compound of Formula II). The specification describing these nitric oxide

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donor compounds is the same in both applications, and the claims for the nitric oxide donor compounds in the grandparent application were not restricted to Groups I to VII.

Applicants also direct the Examiner's attention to great grandparent application, U. S. Serial No. 08/595,538, issued as U. S. Patent 5,932,538, that has claims directed to:

1. Compounds and compositions comprising a nitrosated/nitrosylated compound of Formula III.
2. Compositions comprising (i) a nitrosated/nitrosylated compound of Formula III and (ii) a NO generating compound.
3. Methods for the treatment of male impotence by administration of a composition comprising a nitrosated/nitrosylated compound of Formula III.
4. Methods for the treatment of male impotence by administration of a composition comprising (i) a nitrosated/nitrosylated compound of Formula III and (ii) a NO generating compound.

In great grandparent U. S. Patent No. 5,932,538, Examiner Celsa allowed claims that included the nitrosated/nitrosylated compound of Formula III in combination with all nitric oxide donors (i.e., a compound donates, transfers or releases nitrogen monoxide, induces the production of endogenous endothelium-derived relaxing factor, stimulates endogenous synthesis of nitrogen monoxide or is a substrate for nitric oxide synthase). In the present application, the claims are directed to the nitric oxide donor compounds alone (i.e. without the nitrosated/nitrosylated compound of Formula III). There was no restriction requirement in the great grandparent application with respect to the nitric oxide donors.

Other allowed U.S. patents that contain claims for nitric oxide donor compounds are U. S. Patent Nos. 5,874,437, 5,958,926, 6,043,233, 6,048,858, 6,057,347, 6,083,515, 6,133,272, 6,172,060, 6,172,068, 6,177,428, 6,197,778, 6,197,782. Again, there was no restriction requirement in any of these application with respect to the nitric oxide donor compounds.

In view of the fact that numerous applications have been examined and allowed with the NO donor compounds, and that no election of species or restriction requirement was issued for the individual NO donor compounds in any of these other applications, Applicants respectfully submit that the election of species and restriction requirement in the present application is improper and respectfully request that it be withdrawn.

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Applicants respectfully submit examining pending claims 35-69 together would not place a serious burden on the Examiner, because the compounds in Groups I to VII do not have a separate classification in the art; do not have a separate status in the art; and do not require a different field of search. See MPEP 808.02. Also as discussed above, claims with the NO donor compounds were examined together and allowed in numerous other applications.

**II. Proposed restriction requirement**

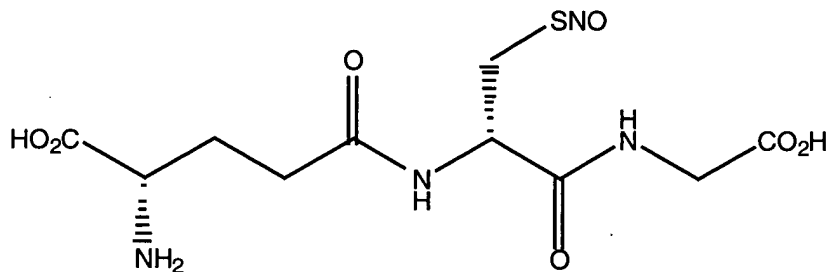
Applicants respectfully propose that all the pending claims 35-69 be examined together

**III. Provisional Response to Restriction Requirement**

Applicants provisionally elect Group VI, drawn to a composition comprising S-nitrosothiol compounds for the treatment of impotence, with traverse.

**IV Election of Species**

In response to the election of species requirement, Applicants provisionally elect S-nitroso-glutathione with traverse. S-nitroso-glutathione is represented by the following structure:



Applicants note that claims 61-65 read on the elected species.

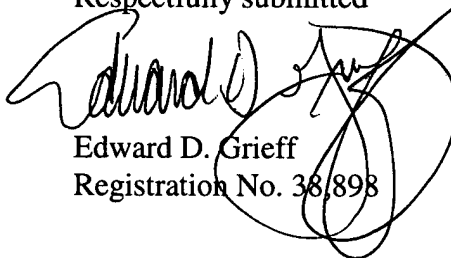
**V. Conclusion**

Applicants respectfully request that the restriction requirement be withdrawn, and replaced with Applicant's proposed restriction requirement.

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An early and favorable consideration and allowance of the claims 35-69 is respectfully requested.

Respectfully submitted



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